DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

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WARNING LETTER
OFL-02-00

FEB 1 2000

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Bello
CEO
South Beach Beverage Company
40 Richards Avenue
Norwalk, Connecticut 06854

Dear Mr. Bello:

The Food and Drug Administration (FDA) has reviewed the labels for your Orange Tomato Elixir, Cranberry Grapefruit Elixir, Wisdom, Power, and Red Tea beverages. Our review reveals that these labels cause the above products to be in violation of section 403 of the Federal Food, Drug and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101 – Food Labeling, as follows.

Orange Tomato Elixir

The product is misbranded under section 403(i)(2) of the Act in that it is a food which purports to be a beverage containing fruit and vegetable juice and fails to bear a statement, on the information panel, of the total percentage of such fruit and vegetable juice contained in the food (21 CFR 101.30).

The product is further misbranded under section 403(i)(1) in that its label fails to bear the common or usual name of the food in accordance with the requirements of 21 CFR 102.33. In accordance with these requirements, the common or usual name for this beverage must indicate that the orange and tomato juices are not the only juices in the product (21 CFR 102.33(c)) and either indicate that the tomato juice is present as a flavor or include the amount of tomato juice declared in a 5% range (21 CFR 102.33(d)). In addition, the orange and tomato juices are from concentrate, therefore, the name must include a term indicating that fact, such as "from concentrate" or "reconstituted" (21 CFR 102.33(g)(1)).

This product is misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears nutrient content claims that are not authorized by regulation or the Act or are not consistent with an existing nutrient content claim regulation. The claims include

"3C's PLUS LYCOPENE" and "CALCIUM CARNITINE CHROMIUM PLUS LYCOPENE." In the context used on this label, these claims imply that this beverage contains a "good source" of calcium, carnitine and chromium and that it also meets the definition for "plus" for lycopene.

The definition for "good source" is based on established reference values and requires, in part, that the food contains 10-19% of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed (21 CFR 101.54(c)). The reference amount customarily consumed for beverages is 240 ml. Since an RDI or DRV for carnitine has not been established, there is no basis for an implied good source claim for carnitine on this label. Since the nutrition label states that the product contains less than 10% of the RDI of calcium per 240 ml, a claim that implies the product is a good source (10-19% of the RDI) of calcium is not consistent with an authorizing regulation and further misbrands the food.

FDA has defined the nutrient content claim "plus" in 21 CFR 101.54(e). Plus can be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium. Since lycopene is not one of these substances, "PLUS LYCOPENE" is an unauthorized nutrient content claim. Because the claim is not authorized as a nutrient content claim by regulation of by the act, the claim misbrands the product. (62 FR 31339, 6/9/97)

The product is misbranded within the meaning of section 403(q) of the Act in that the label implies that this beverage is a good source of chromium but fails to declare the level of chromium expressed as a percentage of the RDI in the nutrition information. (21 CFR 101.9(c)(8)(ii)). Further, the product cannot bear a good source nutrient content claim about chromium unless it contains at least 10 - 19% of the RDI of chromium per 240 ml.

Cranberry Grapefruit Elixir

The product is misbranded under section 403(i)(2) of the Act in that it is a food which purports to be a beverage containing fruit juice and fails to bear a statement, on the information panel, of the total percentage of such fruit juice contained in the food (21 CFR 101.30.)

The product is further misbranded under section 403(i)(1) in that its label fails to bear the common or usual name of this food in accordance with the requirements of 21 CFR 102.33. The common or usual name for this beverage must indicate that the cranberry and grapefruit juices are not the only juices in the product (21 CFR 102.33(c)) and either indicate that the cranberry and grapefruit juices are present as flavor or include the amount of these juices declared in a 5% range (21 CFR 102.33(d)). Since the cranberry and grapefruit juices are from concentrate, the common or usual name must include a term indicating that fact, such as "from concentrate" or "reconstituted" (21 CFR 102.33(g)(1)).

This product is misbranded within the meaning of section 403(r)(1)(B) of the Act in that the label bears the health claim "CARNITINE...CONTRIBUTES TO THE REDUCTION OF CHOLESTEROL" which is not authorized as a health claim by regulation or by the act.

This product is misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears nutrient content claims that are not authorized by regulation or the Act or are not consistent with an authorizing regulation. The claims include "...JUICES ENHANCED WITH OUR EXCLUSIVE 3 C PACKAGE OF CALCIUM ... CHROMIUM...AND CARNITINE..." In the context used on this label the term "enhanced" is considered to be an unauthorized synonym for "added." FDA has defined the nutrient content claim "added" in 21 CFR 101.54(e). "Added" can be used to describe the level of protein, vitamins, minerals, dietary fiber, and potassium, nutrients for which there are established reference values. There is not an established reference value for carnitine. Since carnitine is not one of the substances included in 21 CFR 101.54(e), the claim "ENHANCED WITH ...CARNITINE" is not authorized. Because the claim is not authorized as a nutrient content claim by regulation or by the act, the claim misbrands the product.

The regulation that defines "added" requires, in part, that the food contains at least 10 percent more of the RDI of vitamins or minerals or of the DRV of protein, dietary fiber, or potassium per reference amount customarily consumed than an appropriate reference food (21 CFR 101.54(e)). The reference amount customarily consumed for beverages is 240 ml. Since the beverage does not contain 10% of the RDI of calcium per 240 ml the claim "ENHANCED WITH CALCIUM" misbrands the product.

The product is further misbranded within the meaning of section 403(q) of the Act in that the label bears a claim about the level of chromium but fails to declare the amount of chromium expressed as a percentage of the RDI in the nutrition information (21 CFR 101.9(c)(8)(ii)). Further, the product cannot bear an "added" nutrient content claim about chromium unless it contains at least 10% more of the RDI of chromium per 240 ml than an appropriate reference food.

Wisdom

The product is misbranded under section 403(i)(2) of the Act in that it is a food which purports to be a beverage containing fruit juice and fails to bear a statement, on the information panel, of the total percentage of such fruit juice contained in the food (21 CFR 101.30).

The product is further misbranded in that it fails to bear an appropriate statement of identity that identifies the food by its common or usual name in accordance with the requirements of 21 CFR 101.3, 102.5, and 102.33.

This product is misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears unauthorized nutrient content claims. The claims include "...JUICE ENHANCED WITH HERBS WHOSE PROPERTIES PROMOTE CALM AND FOCUSED THOUGHT, GINKGO..., ST. JOHN'S WORT... AND GOTU KOLA ..." In the context used on this label the term "enhanced" is considered to be an unauthorized synonym for "added" which, as stated above "added" is defined by regulation and may be used to describe the level of certain substances (21 CFR 101.54(e)), provided these substances have established reference values. There is no established reference value for Ginkgo, St John's Wort or Gotu Kola. Since Ginkgo, St John's Wort and Gotu Kola are not one of the substances included in 21 CFR 101.54(e), the claim "ENHANCED WITH...GINKGO...,ST. JOHN'S WORT... AND GOTU KOLA..." is not an authorized claim. Because the claim is not authorized as a nutrient content claim by regulation or by the act, the claim misbrands the product.

Power

The product is misbranded under section 403(i)(2) of the Act in that it is a food which purports to be a beverage containing fruit juice and fails to bear a statement, on the information panel, of the total percentage of such fruit juice contained in the food (21 CFR 101.30).

The product is further misbranded in that it fails to bear an appropriate statement of identity that identifies the food by its common or usual name in accordance with the requirements of 21 CFR 101.3, 102.5, and 102.33.

This product is also misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears unauthorized nutrient content claims. The claims include "...CHARGED WITH ... PROLINE ... CREATINE ... AND TAURINE ..." In the context used on this label the phrase "CHARGED WITH" is considered to be an unauthorized synonym for "added." As we stated previously, "added" is defined by regulation and may be used to describe the level of certain substances, provided these substances have established reference values. There is no established reference value for proline, creatine and taurine. Since proline, creatine and taurine are not one of the substances included in 21 CFR 101.54(e), the claim "...CHARGED WITH ... PROLINE ... CREATINE ... AND TAURINE ..." is not an authorized claim. Because the claim on this product is not authorized as a nutrient content claim by regulation or by the act, the claim misbrands the product.

Red Tea

The product is misbranded under section 403(i)(2) of the Act in that it is a food which purports to be a beverage containing fruit juice and fails to bear a statement, on the

information panel, of the total percentage of such fruit juice contained in the food (21 CFR 101.30).

This product is also misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears the nutrient content claims "Healthy and delicious," and "Healthy refreshment" but the product does not meet the requirements to bear such a claim.

The term "healthy" is defined under 21 CFR 101.65(d). In order to bear the claim "healthy" a food must, in part, contain at least 10 percent of the RDI or DRV of vitamin A, vitamin C, calcium, iron, protein, or fiber per reference amount customarily consumed. The reference amount customarily consumed for a beverage is 240 ml. In accordance with the information provided on the nutrition information, this product does not contain at least 10 percent of the RDI or DRV of vitamin A, vitamin C, calcium, iron, protein, or fiber per 240 ml." Because the claim is not consistent with an authorizing regulation, the claim misbrands the product.

The product is further misbranded in that it bears the claims "WITH SELENIUM" and "PLUS SELENIUM" but fails to declare the level of selenium expressed as a percentage of the RDI in the nutrition information (See 21 CFR 101.9(c)(8)(ii)). The claims "WITH SELENIUM" and "PLUS SELENIUM" are only permitted if the product meets the requirements specified in 21 CFR 101.54(c) and (e) respectively. The claim "WITH SELENIUM" (21 CFR 101.54(c)) requires, in part, that the product contains at least 10% of the RDI of selenium per reference amount customarily consumed. The claim "PLUS SELENIUM" (21 CFR 101.54(e)) requires, in part, that the product contains 10% more of the RDI of selenium per reference amount customarily consumed than an appropriate reference food. The reference amount customarily consumed for a beverage is 240 ml.

In addition, we reviewed the label for Lizard Blizzard. The label for this food bears the statement "...LOADED WITH NATURES MOST POWERFUL COLD AND FLU FIGHTERS" that suggests this product is intended to treat, prevent, cure, or mitigate disease, namely the common cold and influenza. The claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the Act and thus would be subject to regulation under the drug provisions of the Act.

The above violations are not meant to be an all inclusive list of deficiencies on your product labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Under the act, any ingredient intentionally added to a conventional food like these beverages must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. The use of a food ingredient that is neither GRAS nor an approved food additive causes a food to be adulterated under section 402(a)(2)(C) of the act.

We note several ingredients in your product that have neither been approved for such use as food additives nor are we aware of a basis for considering their use to be GRAS. For example, although proline was once considered to be GRAS for use under conditions of good manufacturing practice, safety concerns about excessive levels of individual amino acids in foods caused FDA to revoke that status and prescribe safe conditions of use in a food additive regulation. The food additive regulation limits the use of amino acids in conventional foods to levels intended to significantly improve the biological quality of the total protein in a food containing naturally occurring, primarily intact protein that is considered a significant dietary protein source (21 CFR 172.320). Similarily, FDA has not approved the use of chromium picolinate, lycopene, Echinacea, *gingko biloba*, guarana, St. Johns Wort, or gotu kola, and we are not aware of a basis for concluding that their use in conventional foods is GRAS.

In addition to the claims identified above, we are also concerned about other statements on the labels of your products. The labels for some of your beverages bear statements that describe the effects of certain substances on the structure or function of the body. These claims include suggestions that certain ingredients "...ELIMINATE FAT AND BUILD LEAN MUSCLE MASS...," "...PROMOTE CALM AND FOCUSED THOUGHT," and "...SHARPEN THE MIND." These claims may not appear on your food labels unless they are truthful and not misleading and the claimed effect is achieved through nutritive value.

Articles, other than a food, that are intended to affect the structure or function of the body of man are drugs under section 201(g)(1)(C) of the Act. However, a food label or labeling may bear statements about a substance's effect on the structure or function of the body. Such effects on the structure or function of the body must be achieved through nutritive value and the statement about the effects may not claim to diagnose, mitigate, treat, cure, or prevent disease. A structure-function claim on a food that is not achieved through nutritive value may render the product a drug under section 201(g)(1)(C) of the Act.

We also note that the type size for the manufacturer's name and address does not meet the minimum 1/16 inch specified in 21 CFR 101.2. The type size of the net quantity of contents statements does not meet the minimum 1/8 inch for product containers with an area of the principal display panel of more than 5 but less than 25 square inches (21 CFR 101.105(i)(2)). The smallness of the type size makes these mandatory elements difficult to read on the labels we reviewed.

Please notify this office within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Your letter should also include your basis for concluding that the structure/function claims on your products and the ingredients you use meet the requirements as outlined above. Copies of revised labels for the products should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Office of Food Labeling, 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/S/

John B. Foret
Director
Division of Programs
and Enforcement Policy
Office of Food Labeling
Center for Food Safety
and Applied Nutrition